

17T



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,309	01/03/2001	Christine Andreoni	PF82PCTSEQ/d	7033
25666	7590	04/07/2004	EXAMINER	
THE FIRM OF HUESCHEN AND SAGE 500 COLUMBIA PLAZA 350 EAST MICHIGAN AVENUE KALAMAZOO, MI 49007			SHAHNAN SHAH, KHATOL S	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/647,309

Applicant(s)

ANDREONI ET AL.

Examiner

Khatol S Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12/16/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-24 and 26-40 is/are pending in the application.
- 4a) Of the above claim(s) 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-24 and 26-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 22-24 and 26-40 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1645

***DETAILED ACTION***

1. Applicants' response and amendment 12/16/2003 is acknowledged. Claims 22, 23, 24 and 26-39 have been amended. Claim 25 has been canceled. Specification page 7, lines 26-39 have been amended.
2. Claims 22-24 and 26-40 are pending in this application. Claim 40 is withdrawn from consideration as being drawn to a non-elected invention.
3. Claims 22-24 and 26-39 are under consideration.

***Prior Citations of Title 35 Sections***

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

***Objections Withdrawn***

5. Objection to the abstract made in paragraph 11 of the office action mailed 2/11/2003 is withdrawn in view of applicants' arguments.
6. Objection to the priority statement made in paragraph 10 of the office action mailed 2/11/2003 is withdrawn in view of applicants' arguments.
7. Objection to the specification made in paragraph 8 of the office action mailed 6/17/2003 is withdrawn in view of applicants' amendments.

***Rejections Moot***

8. Rejection of claim 25 under 35 U.S.C. 101 made in paragraph 11 of the office action mailed 6/17/2003 is moot in view of applicants' cancellation of said claim.
9. Rejections of claim 25 under 35 U.S.C. 112 made in paragraphs 11 and 12 of the office action mailed 6/17/2003 are moot in view of applicants' cancellation of said claim.

Art Unit: 1645

10. Rejections of claim 25 under 35 U.S.C. 102 made in paragraphs 14 and 15 of the office action mailed 6/17/2003 are moot in view of applicants' cancellation of said claim.

***Rejections Withdrawn***

11. Rejection of claims 22-24 and 26-39 under 35 U.S.C. 101 made in paragraph 11 of the office action mailed 6/17/2003 is withdrawn in view of applicants' amendments.

12. Rejection of claims 22-24 and 26-39 under 35 U.S.C. 112 made in paragraph 11 and 12 of the office action mailed 6/17/2003 are withdrawn in view of applicants' amendments.

13. Rejections of claims 22-24 and 26-39 under 35 U.S.C. 102 made in paragraphs 14 and 15 of the office action mailed 6/17/2003 are moot in view of applicants' amendments.

***New Rejections***

***Claim Rejections - 35 USC § 112***

14. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "The method" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1645

16. Claims 22-24 and 26- 39 are rejected under 35 U.S.C. 103(a) as being obvious over Rauly et al. (Research in Immunology, Vol. 149, No.1, pp. 99, January 1998) in view of Cooper et al. (Journal of infectious, Vol. 147, No.2, pp. 312-317, February 1983).

Claims are drawn to a method of improving immunity in a mammal through administration of a pharmaceutical composition comprising *Klebsiella pneumoniae* outer membrane protein.

Rauly et al. teach a method of using an outer membrane protein (OmpA) of *Klebsiella pneumoniae* for enhancing or improving immunity of a mammal with respect to an antigen (see page 99). Rauly et al. teach a protein obtained by recombinant process. Rauly et al. teach use of the G1 antigen of RSV coupled to rP40 protein of *Klebsiella pneumoniae* the same conjugate as the claimed invention. Rauly et al. teach that the conjugate generated strong antibody response even in the absence of any adjuvant. Rauly et al. do not teach intranasal administration.

However Cooper et al. teach intranasal administration of *Klebsiella pneumoniae* antigens in mice (see abstract). It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the methods of Rauly et al. and Cooper et al. to obtain the claimed invention. One of ordinary skill in the art would have been motivated to administer the pharmaceutical composition of Rauly et al. intranasally by the teachings of Cooper et al. that protection from disease also follows after intranasal immunization of *Klebsiella pneumoniae* and antibodies develop in the serum after intranasal immunization (i.e improving immunity).

17. Claims 22-24 and 26- 39 are rejected under 35 U.S.C. 103(a) as being obvious over Haeuw et al. (European Journal of Biochemistry, Vol. 255, pp. 446-454, 1998) in view of Cooper et al. (Journal of infectious, Vol. 147, No.2, pp. 312-317, February 1983).

Art Unit: 1645

Claims are drawn to a method of improving immunity in a mammal through administration of a pharmaceutical composition *Klebsiella pneumoniae* outer membrane protein.

Haeuw et al. teach using an outer membrane protein (OmpA) of *Klebsiella pneumoniae* for enhancing or improving immunity of a mammal with respect to an antigen (see abstract). Haeuw et al. teach a protein obtained by recombinant process (see cloning and expression page 447). Haeuw et al. teach detergent Zwittergent 3-14 (see reagents page 447). Rauly et al. teach use of the G1 antigen of RSV coupled to rP40 protein of *Klebsiella pneumoniae* the same conjugate as the claimed invention (page 447). Haeuw et al. teach that the conjugate generated strong antibody response even in the absence of any adjuvant (see pages 448 and 451). Haeuw et al. do not teach intranasal administration. However Cooper et al. teach intranasal administration of *Klebsiella pneumoniae* antigens in mice (see abstract). It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the methods of Rauly et al. and Cooper et al. to obtain the claimed invention. One of ordinary skill in the art would have been motivated to administer the pharmaceutical composition of Rauly et al. intranasally by the teachings of Cooper et al. that protection from disease also follows after intranasal immunization of *Klebsiella pneumoniae* and antibodies develop in the serum after intranasal immunization (i.e improving immunity).

### ***Conclusion***

18. No Claims are allowed.

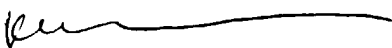
19. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner, Art Unit 1645, April 2, 2004

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER